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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/524,376	10/14/2005	Joel Melnick	6963US01	6963US01 8833	
	23492 7590 11/30/2007 ROBERT DEBERARDINE EXAMINER				
ABBOTT LABORATORIES			JAVANMARD, SAHAR		
	100 ABBOTT PARK ROAD DEPT. 377/AP6A		ART UNIT	PAPER NUMBER	
ABBOTT PARK, IL 60064-6008		1617			
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			NOTIFICATION DATE	DELIVERY MODE	
			11/30/2007	ELECTRONIC	

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Legal\_Patents@abbott.com Cassie.Gray@abbott.com

		Application No.	Applicant(s)		
Office Action Summary		10/524,376	MELNICK ET AL.		
		Examiner	Art Unit		
	·	SAHAR JAVANMARD	4133		
Period fo	The MAILING DATE of this communication app r Reply	ears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status		;			
<ol> <li>Responsive to communication(s) filed on <u>15 February 2005</u>.</li> <li>This action is FINAL. 2b) This action is non-final.</li> <li>Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</li> </ol>					
Disposition of Claims					
5)	Claim(s) 1-18 is/are pending in the application.  4a) Of the above claim(s) is/are withdray Claim(s) is/are allowed.  Claim(s) is/are rejected.  Claim(s) is/are objected to.  Claim(s) 1-18 are subject to restriction and/or expressions.	vn from consideration.			
Application Papers					
10) 🗌 .	The specification is objected to by the Examine The drawing(s) filed on is/are: a) ☐ access Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex	epted or b) objected to by the drawing(s) be held in abeyance. Se ion is required if the drawing(s) is ob	ee 37 CFR 1.85(a). ojected to. See 37 CFR 1.121(d).		
Priority u	nder 35 U.S.C. § 119				
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	Date		

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### **DETAILED ACTION**

#### Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group I, claim(s) 1-5, are drawn to a formulation containing a therapeutically effective amount of at least one Vitamin D compound or analog.
- II. Group II, claim(s) 6-18, are drawn to a method of shortening hospital stays and improving survival in chronic kidney disease patients, said method comprising the step of administering a composition containing a therapeutically effective amount of at least one Vitamin D compound or analog without titrating to serum PTH or serum calcium, wherein hospital stays and survival are shortened compared to chronic kidney disease patients not receiving any Vitamin D compound or analog-containing composition.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

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In this case, Teng (*New England Journal or Medicine*, **349 (5)**, 2003, pp 446-456) discloses that patients who receive paricalcitol (a vitamin D analog) while undergoing long-term hemodialysis appear to have a significant survival advantage over those who receive calcitriol (abstract).

As a result, no special technical features exist among the different groups because the inventions in Groups I and II fail to make a contribution over the prior art with respect to novelty and inventive step. In conclusion, there is a lack of unity of invention, and therefore restriction for examination purposes is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

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unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### Conclusion -

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY STUCKER can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SJ

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